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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,887	03/08/2004	Peter M. Bonutti	780-A04-012-1A	3185

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EXAMINER
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CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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08/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/795,887	<b>Applicant(s)</b> BONUTTI, PETER M.	
	<b>Examiner</b> JERRY CUMBERLEDGE	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-15 and 19-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-36 is/are allowed.
- 6) ☒ Claim(s) 1,4-15 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the skim cut" in line 20. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 19 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whiteside (US Pat. 4,474,177).

Whiteside discloses a method of performing a total knee arthroplasty surgery on a patient's joint, the method comprising, in the following order: forming an incision (column 7, lines 64-68); positioning a guide member at least part ways through the incision, against a bone of the joint, the guide member having a guide surface (column 9, lines 30-61); initiating a cut in the bone while guiding a cutting tool along the guide surface to

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form a cut surface (column 9, lines 56-61), at least a portion of said cut bone being located in the interior of the body with respect to the incision (since cutting is happening within the incision); removing the guide member from against the bone of the joint (column 9, lines 62-64); positioning the cutting tool through the incision, and continuing the cut in the bone while guiding the cutting tool along the cut surface (column 9, lines 62-64), positioning a first portion of a total knee replacement component against the cut bone on one side of a joint (column 11, lines 18-24), and subsequently positioning a second portion of the total knee replacement component against the cut bone on the same side of the joint (column 11, lines 18-24); and connecting the first and second portions of the total knee replacement component together after both portions have been positioned against the cut bone within the body (column 11, lines 18-24), each of the first and second portions of the total knee replacement component having an articulating surface (column 11, lines 18-24). The method further including the step of suspending a distal portion of a patient's extremity connected with the joint (column 7, lines 64-68), and initiating the cut and completing the cut are performed while the distal portion of the patient's extremity connected with the joint is suspended (column 7, lines 64-68). Initiating the cut and completing continuing the cut are performed on a condyle of the bone, and further including positioning a partial joint replacement component against the cut condyle of the bone (Fig. 22, Fig. 23). The cut is completed while guiding the cutting tool along the cut surface (column 9, lines 62-64, since rough cut is only made if needed). The method further includes removing the guide member from the bone before continuing the cut (column 9, lines 62-64). The guide surface comprises a

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guide slot and the step of positioning a cutting tool includes inserting the cutting tool into the guide slot (Fig. 17, ref. 64).

Whiteside discloses the claimed invention except for explicitly stating that the incision is about 13 cm or less. It would have been an obvious matter of design choice to have made the incision to be about 13 cm or less, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, at least some of the guides disclosed by Whiteside appear to have widths much smaller than 13 cm (e.g. column 4, lines 34-39)(column 5, lines 15-31). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method with incisions that are smaller than 13 cm to better conform to the sizes of the components of Whiteside and to make the incisions as small as possible, in order to reduce trauma to the patient.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whiteside (US Pat. 4,474,177) in view of Sherwin (US Pat. 3,750,652).

Whiteside discloses the claimed invention except for the step of distracting the joint, and wherein at least one of the steps of positioning the guide member, positioning the cutting tool, initiating the cut, and completing the cut is performed with the joint distracted.

Sherwin discloses distracting the knee (column 1, lines 58-67) during a surgical procedure (column 1, lines 1-10), in order to allow increased visibility to the area that the surgery is being performed on (column 1, lines 40-41 and column 1, lines 58- 67).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Whiteside with a step of distracting the knee as taught by Sherwin, in order to allow increased visibility to the area that the surgery is being performed on (column 1, lines 40-41 and column 1, lines 58- 67).

#### ***Allowable Subject Matter***

Claims 1 and 4-14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 26-36 are allowed.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733